

Attorney Docket No.: PTQ-0028
Inventors: Van Eyk et al.
Serial No.: 09/419,901
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REMARKS

Claims 1-7, 15-28, 31, 34, 35 and 37-41 are pending in the instant application. Claims 1-7, 15-28, 31, 34, 35 and 37-41 have been rejected. Claims 1 and 35 have been amended. Support for this amendment is provided in the specification at page 14, lines 11-26. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Information Disclosure Statement

It is respectfully pointed out that the listing of references in the specification was not meant by Applicants to serve as the Information Disclosure Statement in the instant application. Applicants submitted Information Disclosure Statement pursuant to 37 C.F.R. 1.56 and in accordance with 37 C.F.R. 1.97-1.98 and inclusive of copies of all references listed therein on April 13, 2000 and January 21, 2004.

II. Obviousness-type Double Patenting Rejection

Claims 1-7, 15-28, 31, 34-35 and 37-41 remain provisionally rejected under the judicially created doctrine

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of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 09/115,589. The Examiner has agreed, however, to hold this rejection in abeyance until one of the application is allowed. Should an obviousness-type double patenting issue still exist at that time, Applicants will file the appropriate terminal disclaimer.

III. Rejection of Claims 1, 15 and 16 under 35 U.S.C.

102(b)

Claims 1, 15 and 16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wicks et al. (WO 94/27156).

The Examiner has acknowledged that the disclosure of Wicks et al. merely teaches detection of TnI as it relates to muscle damage. However, the Examiner "takes TnI to be a protein meeting the limitation of a myofilament protein modification product being a chemical adduct of a myofilament protein." The Examiner points to the disclosure in Wicks et al. at page 1, lines 17-22, page 4, lines 5-8, page 30 and page 50 in support of this suggestion. Further, the Examiner suggests that claim reads on instances where the chemical adduct is "absent". The Examiner also suggests

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that the only required detection is a myofilament protein modification product which TnI meets.

Accordingly, in an earnest effort to advance the prosecution of this case Applicants have deleted the phrase "or absence" from claim 1. Further Applicants have amended claim 1 to clarify that it is the presence of at least one myofilament protein modification product which is a chemical adduct of a myofilament protein that is an indicator of muscle damage in the subject.

Applicants respectfully disagree with the Examiner's suggestion that teachings of Wicks relating to TnI meet the limitation of a myofilament protein modification product being a chemical adduct of a myofilament protein. Chemical adduct is defined in the instant specification at page 14, lines 11-26. As made clear in this definition, by chemical adduct it is meant a post-translational modification of intact myofilament proteins, of degradation products thereof or protein-protein complexes of myofilament proteins.

Nowhere does Wicks teach methods for detecting such chemical adducts nor the relationship of such chemical adducts to muscle damage.

In an earnest effort to advance the prosecution and to clearly distinguish the present invention which relates to detection of a chemical adducts of a myofilament protein

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from prior art teachings such as Wicks et al., Applicants have amended claim 1 to state that the chemical adduct of the myofilament protein is a post-translational modification of an intact myofilament protein, a post-translational modification of a degradation product of a myofilament protein or a post-translation modification of a protein-protein complex of myofilament proteins.

As Wicks does not teach a method for detection of such chemical adducts, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. 102(b) is therefore respectfully requested.

IV. Rejection of Claims 2-7, 17-28, 31, 33-35 and 37-41 under 35 U.S.C. 103(a)

Claims 2-7, 17-28, 31, 33-35 and 37-41 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Wicks et al. (WO 94/27156) in view of Wicks et al. (U.S. Patent 5,834,220) and in further view of Van Eyk et al. (U.S. Patent 6,248,549).

Applicants respectfully traverse this rejection.

AS discussed in Section III, supra, the claims of the instant application have been amended to clarify that the

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chemical adduct of the myofilament protein detected in the present invention is a post-translational modification of an intact myofilament protein, a post-translational modification of a degradation product of a myofilament protein or a post-translation modification of a protein-protein complex of myofilament proteins.

Nowhere do Wicks (WO 94/27156) or Wicks et al. (U.S. Patent 5,834,220) teach or suggest detection of such chemical adducts.

Further, Van Eyk et al. (U.S. Patent 6,248,549) is an invalid prior art reference with respect to the instant invention as it issued subsequent to the filing date of the instant application and is not by another. U.S. Patent 6,248,549 and the instant application have a common inventor, Dr. Jennifer Van Eyk. Applicants are submitting a Declaration by Dr. Van Eyk herewith which states that any invention disclosed, but not claimed in U.S. Patent 6,248,549 was derived from her work and thus is not an invention "by another". Thus, U.S. Patent 6,248,549 is not a valid prior art reference with respect to the instant application.

Accordingly, since the cited combination of valid prior art references does not teach or suggest all the limitations

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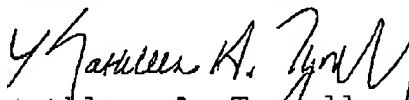
of the instant claimed invention, it cannot render the
instant claimed invention prima facie obvious.

Withdrawal of this rejection under 35 U.S.C. 103(a) is
therefore respectfully requested.

V. Conclusion

Applicants believe that the foregoing comprises a full
and complete response to the Office Action of record.
Accordingly, favorable reconsideration and subsequent
allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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